



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR      | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|---------------------------|---------------------|------------------|
| 10/501,856  | 11/29/2004  | Nicole Lesley Prokopishyn | BRMZ-P02-004        | 7139             |
| 28120   | 7590        | 03/22/2007                | EXAMINER            |                  |
| FISH & NEAVE IP GROUP<br>ROPES & GRAY LLP<br>ONE INTERNATIONAL PLACE<br>BOSTON, MA 02110-2624 |             |                           | ZHENG, LI           |                  |
|   |             |                           | ART UNIT            | PAPER NUMBER     |
|   |             |                           | 1638                |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE  |             | MAIL DATE                 | DELIVERY MODE       |                  |
| 3 MONTHS  |             | 03/22/2007                | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                        |                            |  |
|------------------------------|------------------------|----------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>        |  |
|                              | 10/501,856             | PROKOPISHYN, NICOLE LESLEY |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>            |  |
|                              | Li Zheng               | 1638                       |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 July 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1282005</u> .   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 14 is objected to because the claim is mistakenly marked as an original claim.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitation, "another nucleic acid", renders the claim indefinite. It is unclear what the recitation encompasses. Does "another nucleic acid" refer to a sequence in ssDNA or anywhere else in the genome? The metes and bounds are not clear. Further, the recitation, "having essentially the sequence of the targeted gene as

Art Unit: 1638

modified", renders the claim indefinite. The specification defines the term on page 9. However, it is unclear what is exactly excluded and encompassed by the recitation. How many modifications are allowed? The metes and bounds are not clear.

In claim 2: the recitation, "substantially", renders the claim indefinite. The term is a relative term with no definite meanings. It is unclear what is considered to be substantial. The metes and bounds are not clear.

In claim 13: the recitation, "target gene as modified", renders the claim indefinite. It is unclear how many modifications are allowed. The metes and bounds are not clear.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Court et al. (U.S. Patent No. 7,144,734) in view of Applicants' admitted prior art (page 6, lines 10-21).

Court et al. teach a method for inserting a nucleotide sequence into a target in plant cell comprising 1) introducing into the host cell a modified ssDNA of at least 30 nucleotide sequence in length wherein the host cell expresses ssDNA binding protein,

2) inducing homologous recombination between the ssDNA and the target nucleotide sequence and thereby introducing the modified nucleotide sequence into the target sequence (claim 7). The specification also teach ssDNA can be synthesize so that it is inherently free of a complementary DNA (column 43, lines 28-35). Further, the specification teaches ssDNA can be transferred into the protoplasts by microinjection (column 51, lines 55-56). The specification also teach the method can be used to modify various storage protein in wheat and corn to increase the nutritional value (column 52, lines 24-33). The specification also teach that ssDNA could be 70-1000 nucleotides in length (column 30, lines 41-42)

Court et al. do not teach the ssDNA is 400 and 800 nucleotides in length. Court et al. do not teach the method of making ssDNA by separating biotinylated strand from non-biotinylated strand. Court et al. do not teach modifying target genes of ALS and EPSPS.

In specification, the Applicants admit that modifying ALS and EPSPS genes to generate herbicide resistant alleles is well known in prior art (page 6, lines 10-21).

It would have been obvious for a person with ordinary skill in the art to use the method of Court et al. to modify ALS and EPSPS, given that Applicants' admitted prior art teaches modifying ALS and EPSPS genes to generate herbicide resistant alleles could generate a herbicide resistant plant.

It would also have been obvious for a person with ordinary skill in the art to modify the method of Court et al. and generate ssDNA by PCR amplification using

biotinylated primer as one of the primers followed by separating biotinylated strand from non-biotinylated strand, given that this is a routine technique to generate ssDNA.

It would also have been obvious for a person with ordinary skill in the art to use ssDNA of 400-800 nucleotides in length, given that this is merely an optimization within the range (70-1000 nt) taught by Court et al.

4. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bilang et al. (1992 Molecular and Cellular Biology 12:329-336) in view of Applicants' admitted prior art (page 6, lines 10-21).

Bilang et al. teach a method for measuring homologous recombination efficiency by using ssDNA of with 420 bps of homologous sequence with target sequence (abstract, page 30, 1<sup>st</sup> paragraph of the RESULT section and Figure 1) in tobacco. The specification also teach ssDNA can be synthesize so that it is inherently free of a complementary DNA (page 30, 3<sup>rd</sup> paragraph of the RESULT section).

Bilang et al. do not teach the ssDNA is 400 and 800 nucleotides in total length. Bilang et al. do not teach the method of making ssDNA by separating biotinylated strand from non-biotinylated strand. Bilang et al. do not teach modifying target genes of ALS and EPSPS.

In specification, the Applicants admit that modifying ALS and EPSPS genes to generate herbicide resistant alleles is well known in prior art (page 6, lines 10-21).

It would have been obvious for a person with ordinary skill in the art to use the method of Court et al. to modify ALS and EPSPS, given that Applicants' admitted prior

Art Unit: 1638

art teaches modifying ALS and EPSPS genes to generate herbicide resistant alleles could generate a herbicide resistant plant.

It would also have been obvious for a person with ordinary skill in the art to modify the method of Bilang et al. and generate ssDNA by PCR amplification using biotinylated primer as one of the primers followed by separating biotinylated strand from non-biotinylated strand, given that this is a routine technique to generate ssDNA.

It would also have been obvious for a person with ordinary skill in the art to use ssDNA of 400-800 nucleotides in length, given that this is merely an optimization and the teaching of Bilang et al. that the homologous region is 420 bp.

### ***Conclusion***

Claims 1-20 are rejected.

No claim is allowed.

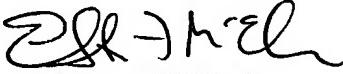
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone

Art Unit: 1638

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ELIZABETH MC ELVAIN  
PRIMARY EXAMINER